

Policy No: BEN 06-001
Subject: Erectile Dysfunction Medication(s)
Approved by: J.D. Hickey

PURPOSE:

The purpose of this policy is to clarify the coverage for Erectile Dysfunction (ED) medications (Viagra®, Levitra®, Cialis®) and the circumstances in which these drugs can be dispensed to a TennCare enrollee.

POLICY:

The Bureau of TennCare does not authorize the prescribing of <u>any</u> drug specifically for the treatment of male impotence. Viagra®, Cialis® and Levitra® are the only FDA approved medications for this treatment. Federal regulations (Sec 1927 [42USC 1396 r-8](d)(1) allow the State to restrict coverage of any outpatient drug if the State has excluded coverage of the drug from its formulary and allows the establishment of procedures for prior authorization of certain outpatient drugs. Currently, the only FDA-approved indication for Viagra <u>is</u> for male impotence but a common "off-label"/non FDA approved use for "Viagra® (sildenafil citrate) is for severe Pulmonary Arterial Hypertension (PAH). Viagra® may be approved for patients who have severe pulmonary hypertension on a **case-by-case** basis with prior authorization.

PROCEDURE:

- Phosphodiesterase inhibitors require diagnosis of severe pulmonary hypertension (defined as systolic pulmonary pressure >80mmg Hg as determined by cardiac catheterization) with documentation of failure of or contraindication to all other available therapies. Documentation must be provided of vasoreactivity testing and consultation with a specialist experienced in the treatment of pulmonary hypertension patients.
- The requesting physician must contact the prior authorization unit of the Pharmacy Benefits Manager (PBM) to secure approval.
- A sole diagnosis of impotence will not be approved.

• If it is shown that the recipient requesting approval is a convicted sex offender, Viagra®, Levitra®, Cialis® (sildenafil citrate) will not be approved.

OFFICES OF PRIMARY RESPONSIBILITY:

Office of the Medical Director Chief Pharmacy Officer

REFERENCES:

SMDL #05-001 Sec 1927 [42USC 1396 r-8] (d)(1) 1200-13-13-.04 (8)(b) 23